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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/756,765 | 01/14/2004 | Per Egnelov | 030481-0212 | 1510 |

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| EXAMINER | |
|---|---|
| MALLARI, PATRICIA C | |
| ART UNIT | PAPER NUMBER |
| 3735 | |

| MAIL DATE | DELIVERY MODE |
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| 03/04/2009 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/756,765 | EGNELOV ET AL. | |
| | Examiner | Art Unit | |
| | PATRICIA C. MALLARI | 3735 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *02 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,3-11,14-16 and 20-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,3-8,10,15,16 and 20-27* is/are allowed.

6)☒ Claim(s) *9 and 11* is/are rejected.

7)☒ Claim(s) *14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

This is a non-final Office action. The indicated allowability of claims 9 and 11 has regretfully been withdrawn. See the rejection set forth below for details.

### *Claim Objections*

Claim 14 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 10. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 1, 10, 14, and 20-22 are objected to because of the following informalities:

On line 10 of claim 1, “the extreme” should be replaced with “an extreme”.

On line 19 of claim 1, “a distal” should be replaced with “the distal”.

On line 19 of claim 10 "a distal" should be replaced with "the distal".

On line 10 of claim 14, “the extreme” should be replaced with “an extreme”.

On line 19 of claim 14, "a distal" should be replaced with "the distal".

On lines 9-10 of claim 20, "the extreme" should be replaced with "an extreme".

On line 19 of claim 20, “a distal” should be replaced with “the distal”.

On line 10 of claim 21, “the extreme” should be replaced with “an extreme”.

On line 19 of claim 21, “a distal” should be replaced with “the distal”.

On line 10 of claim 22, “the extreme” should be replaced with “an extreme”.

On line 19 of claim 22, "a distal" should be replaced with "the distal".

Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,246,426 to Lewis et al. Lewis teaches an indicator device for visually indicating a pressure of blood inside a blood vessel. The device comprises a body 10, the body comprising a duct 70c, 82, 108 extending in the body and having a hemostatically sealed blood accommodating chamber 38, 40 at a proximal end (see entire document, especially figs. 6, 7, 8A & B; col. 5, lines29-36 of Lewis). A distal portion of the body is adapted to be positioned inside the blood vessel and comprises a liquid inlet opening 70b in fluid communication with the duct (see entire document, especially fig. 8B; col. 6, lines 54-64; col. 10, lines 23-34 of Lewis). A window comprises an at least semi-transparent section configured to enable visual observation of blood entering into the duct via the inlet opening when the inlet opening is located inside the blood vessel (see entire document, especially figs. 4, 6B; col. 8, lines 3-10 of Lewis). The duct exhibits a varying cross-section over its length, wherein the duct becomes narrower in the direction of towards the blood accommodating chamber (see

entire document, especially figs. 4, 7, 8A, and 8B of Lewis), wherein figure 8B in particular shows the duct becoming narrower because of the present of the guide wire 16.

Regarding claim 11, Lewis describes a body comprising a passage 54 passing through the body and a duct 70c, 82, 108 extending in the body and having a hemostatically sealed blood accommodating chamber 38, 40, wherein the duct first becomes progressively narrower (due to the presence of guide wire 16) and then becomes progressively wider at internal cavity 82 (see entire document, especially figs. 4, 7, 8A, 8B). An insertion tube 14, 70 comprises a distal end portion adapted to be positioned inside the blood vessel and comprising a fluid communication pathway between a liquid inlet opening 70d near a distal end of the insertion tube and the duct (see entire document, especially fig. 8B; col. 10, lines 23-30 of Lewis). A window comprises an at least semi-transparent section configured to enable visual observation of blood entering into the duct via the inlet opening when the inlet opening is located inside the blood vessel (see entire document, especially figs. 4, 6B, 7; col. 8, lines 3-10 of Lewis). The passage and fluid communication pathway are adapted to permit a member to be threaded in a substantially straight path there through between a distal end and a proximal end of the indicator device.

Applicants are reminded that the member is not positively claimed, and that the path between followed by such a member need only be *substantially* straight.

### *Response to Arguments*

Applicant's arguments, see pp. 12-13, filed 11/10/08, with respect to the Crawford reference have been fully considered and are persuasive. The rejection of claim 1, 3-8, 10, 14, and 20-27 as being anticipated by Crawford has been withdrawn.

### *Allowable Subject Matter*

Claims 1, 3-8, 10, 15, 16, and 20-27 allowed. The allowability of claims 15 and 16 was addressed in previous Office actions filed 4/20/05, 6/30/06, and 5/22/07 and is repeated below.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claims 1, 3-8, 10, and 21-27, the primary reason for allowance is the inclusion of the fluid communication pathway being formed between the insertion tube and the elongated member in combination with the outer dimension of the elongated member and the inner dimension of the insertion tube being configured such that flow of blood between the outer dimension and inner dimension is prevented when the elongated member is inserted into the insertion tube, and further in combination with all of the other limitations of the claims, which is not taught or suggested by the prior art.

Regarding claims 15 and 16, the primary reason for allowance is the inclusion of the blood accommodating chamber and duct being dimensioned such that a counter-pressure therein when the blood enters will cause a blood meniscus at a lowest possible systolic pressure to be located approximately at the spill-over edge or within

the window, in combination with all of the other limitations of the claims, which is not taught or suggested by the prior art. The instant specification discloses that such dimensioning ensures that the chamber volume is adapted to include the expected pressure ranges and all such pressures would be visually detectable and further discloses a lowest possible systolic pressure as about 100 mm Hg (see entire document, especially paragraphs 42-44 of instant specification).

Regarding claim 20, the primary reason for allowance is the inclusion of the fluid communication pathway being formed between the insertion tube and the elongated member in combination with the body and insertion tube being adapted to permit the elongated member to be threaded in a substantially straight path there through between a proximal end of the body and the distal end of the insertion tube to plug the opening at the extreme end of the distal end portion, and further in combination with all of the other limitations of the claims, which is not taught or suggested by the prior art.

## ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PATRICIA C. MALLARI whose telephone number is (571)272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia C. Mallari/
Primary Examiner, Art Unit 3735